



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting. Information about ACHDNC and the agenda for this meeting can be found on ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: Tuesday, November 9, 2021, from 10:00 AM to 3:00 PM Eastern Time (ET) and Wednesday, November 10, 2021, from 10:00 AM to 3:00 PM ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please register online at <https://www.achdncmeetings.org/registration/> by 12:00 PM ET on November 8, 2021. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; (301) 443-0721; or ACHDNC@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing

morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (i.e., policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

During the November 9-10, 2021, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

- 1) The Committee will vote on whether or not to approve the following updates to the Committee's evidence-based review and decision-making process: the condition nomination form, methods for assessing published and unpublished evidence, and additional guidance for the Committee's decision matrix.
- 2) A presentation on phase two of the Mucopolysaccharidosis type II evidence review;
- 3) A presentation on phase one of the Guanidinoacetate methyltransferase deficiency evidence review;
- 4) A Krabbe disease nomination overview;
- 5) A possible Committee vote on whether to move Krabbe disease forward to a full evidence review; and

6) Workgroup updates.

The agenda for this meeting does not include any vote or decision to recommend a condition for inclusion in the Recommended Uniform Screening Panel. As noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (Krabbe disease) to full evidence review, and will hear presentations on evidence review of Mucopolysaccharidosis type II and Guanidinoacetate methyltransferase deficiency, any of which may lead to such a recommendation at a future time. Agenda items are subject to change as priorities dictate. Information about ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments. Public participants providing general oral comments may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12:00 PM ET on Thursday, November 4, 2021.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021-21582 Filed: 10/4/2021 8:45 am; Publication Date: 10/5/2021]